Listing of Claims

1. (currently amended) A method of collecting ~~placental~~ stem cells from an isolated, exsanguinated mammalian placenta, said method comprising:

perfusing said placenta with a perfusion solution in an amount and for a time sufficient to collect a detectable amount of ~~placental~~ stem cells from said placenta, said placenta having been drained of cord blood and flushed to remove residual blood prior to said perfusing, and wherein said perfusing is performed by passing said perfusion solution into one or both of the umbilical artery and umbilical vein of said placenta; and

collecting said ~~placental~~ stem cells and perfusion solution from said placenta.

2-24. (previously cancelled)

25. (currently amended) A method of collecting $CD34^+$ stem cells from an isolated and exsanguinated mammalian placenta, said method comprising:

perfusing said placenta with a perfusion solution in an amount and for a time sufficient to collect a detectable amount of said $CD34^+$ stem cells ~~from said placenta~~, wherein said placenta has been drained of cord blood and flushed to remove residual blood prior to said perfusing, ~~and~~ wherein said $CD34^+$ stem cells are not obtained from cord blood, and wherein said perfusing is performed by passing said perfusion solution into one or both of the umbilical artery and umbilical vein of said placenta; and

collecting said $CD34^+$ stem cells and perfusion solution from said placenta.

26. (currently amended) The method of claim[[s]] 1 [[or 25]] further comprising separating said ~~placental~~ $CD34^+$ stem cells from ~~said residual cells~~ cells other than said $CD34^+$ stem cells and said perfusion solution.

27. (previously added) The method of claim 26, wherein said separating is accomplished by centrifugation.

28. (cancelled)

29. (currently amended) The method of claim[[s]] 1 [[or 25]] wherein said perfusing is performed for at least four hours.

30. (currently amended) The method of claim[[s]] 1 [[or 25]] wherein said perfusing is performed for at least twelve hours.

31. (currently amended) The method of claim[[s]] 1 [[or 25]] wherein said perfusing is performed for at least 24 hours.

32. (currently amended) The method of claim[[s]] 1 [[or 25]] wherein said perfusing is performed using a first volume of between about 30 ml and about 150 ml of said perfusion solution.

33. (previously added) The method of claim 32, further comprising continuing said perfusing using a second volume of about 30 ml to about 150 ml of said perfusion solution, said second volume being collected separately from said first volume.

34. (currently amended) The method of claim[[s]] 1 [[or 25]], in which said perfusing is performed for a plurality of times.

35. (previously added) The method of claim 34, wherein, for each of said times, said perfusing is performed using a volume of about 30 ml to about 150 ml of said perfusion solution.

36. (currently amended) The method of claim 32, further comprising separating said ~~placental~~ $\underline{CD34^+}$ stem cells from said perfusion solution.

37. (previously added) The method of claim 33, further comprising separating said ~~placental~~ $\underline{CD34^+}$ stem cells from said perfusion solution.

38. (previously added) The method of claim 32 wherein said ~~placental~~ $\underline{CD34^+}$ stem cells are collected over a period of up to 48 hours.

39. (previously added) The method of claim 33 wherein said ~~placental~~ $\underline{CD34^+}$ stem cells are collected over a period of up to 48 hours.

40. (currently amended) The method of claim[[s]] 1 [[or 25]] wherein said perfusion solution contains an anticoagulant.

41. (previously added) The method of claim 32 wherein said perfusion solution contains an anticoagulant.

42. (previously added) The method of claim 34 wherein said perfusion solution contains an anticoagulant.

43. (currently amended) The method of claim[[s]] 1 [[or 25]], wherein said perfusion solution comprises heparin, ethylene diamine tetra acetic acid (EDTA) or creatine phosphate dextrose (CPDA).

44. (currently amended) The method of claim[[s]] 1 [[or 25]], wherein said perfusion solution comprises a growth factor or a cytokine.

45. (previously added) The method of claim 44, wherein said growth factor or cytokine is selected from the group consisting of a colony stimulating factor, interferon,

erythropoietin, stem cell factor, thrombopoietin, an interleukin, granulocyte colony-stimulating factor, and a combination of any thereof.

46. (currently amended) The method of claim[[s]] 1 [[or 25]], wherein said isolated mammalian placenta is a post-partum placenta remaining after a successful birth.

47. (new) The method of claim 25 further comprising separating said ~~placental~~ $CD34^+$ stem cells from cells other than ~~placental~~ $CD34^+$ stem cells and said perfusion solution.

48. (new) The method of claim 47, wherein said separating is accomplished by centrifugation.

49. (new) The method of claim 25 wherein said perfusing is performed for at least four hours.

50. (new) The method of claim 25 wherein said perfusing is performed for at least twelve hours.

51. (new) The method of claim 25 wherein said perfusing is performed for at least 24 hours.

52. (new) The method of claim 25, wherein said perfusing is performed using a first volume of between about 30 ml and about 150 ml of said perfusion solution.

53. (new) The method of claim 52, further comprising continuing said perfusing using a second volume of about 30 ml to about 150 ml of said perfusion solution, said second volume being collected separately from said first volume.

54. (new) The method of claim 25, in which said perfusing is performed for a plurality of times.

55. (new) The method of claim 54, wherein, for each of said times, said perfusing is performed using a volume of about 30 ml to about 150 ml of said perfusion solution.

56. (new) The method of claim 52, further comprising separating said ~~placental~~ $CD34^+$ stem cells from said perfusion solution.

57. (new) The method of claim 53, further comprising separating said ~~placental~~ $CD34^+$ stem cells from said perfusion solution.

58. (new) The method of claim 52 wherein said ~~placental~~ $CD34^+$ stem cells are collected over a period of up to 48 hours.

59. (new) The method of claim 53 wherein said ~~placental~~ $CD34^+$ stem cells are collected over a period of up to 48 hours.

60. (new) The method of claim 25 wherein said perfusion solution contains an anticoagulant.

61. (new) The method of claim 52 wherein said perfusion solution contains an anticoagulant.

62. (new) The method of claim 54 wherein said perfusion solution contains an anticoagulant.

63. (new) The method of claim 25, wherein said perfusion solution comprises heparin, ethylene diamine tetra acetic acid (EDTA) or creatine phosphate dextrose (CPDA).

64. (new) The method of claim 25, wherein said perfusion solution comprises a growth factor or a cytokine.

65. (new) The method of claim 64, wherein said growth factor or cytokine is selected from the group consisting of a colony stimulating factor, interferon, erythropoietin, stem cell factor, thrombopoietin, an interleukin, granulocyte colony-stimulating factor, and a combination of any thereof.

66. (new) The method of claim 25, wherein said isolated mammalian placenta is a post-partum placenta remaining after a successful birth.

67. (new) The method of claim 1 or claim 25, wherein said stem cell is totipotent.

68. (new) The method of claim 1 or claim 25, wherein said stem cell is multipotent.

69. (new) The method of claim 1 or claim 25, wherein said stem cell is embryonic-like.

Applicant's Interview Summary

Applicant thanks Examiner Qian Janice Li and Examiner Anne M. Wehbe (collectively, "Examiners") for the courtesy of the in-person interview held on March 9, 2004. Attending for Applicant were Robert J, Hariri, M.D., Ph.D., Maria E. Pasquale, and Lawrence S. Graham (collectively, "Applicant"). During the Interview, the participants discussed the pending Final Office Action ("Office Action"), art of record cited in the Office Action, including Addison *et al.*, Belvedere *et al.*, Boyse *et al.*, and Sanders *et al.*, and a draft Amendment in response to the Office Action. Amendments to the independent claims were discussed, and the Examiners indicated that the amendments would be favorably considered, and that they overcame the art of record.

Applicant reviewed the Belvedere reference, pointing out that this reference represented the state of the stem cell collection art as of the earliest priority date of the present application, and that it taught only the maximization of the collection of blood from the placenta, but not the collection of cells from the placenta itself after substantially all of blood had been removed. Also discussed was that Belvedere did not disclose or suggest that there could be any use of the placenta once compressed to remove the blood. Applicant pointed out that this underscored the nonobviousness of the claimed invention.

In discussing the cited art, the Examiners stated that Sanders taught the perfusion of a placenta. Applicants, in response, stated that the "perfusion" taught by Sanders was passive; that is, the placenta was merely cultured in a bath or culture dish surrounded by circulating medium. Unlike active perfusion, as recited in the claims, such culturing could not be used to collect cells. Thus, Sanders' method and teaching could not be used to collect cells such as stem cells from the placenta.

The Examiners contended that the claims as presented in the draft Amendment, which recited that the placenta was "exsanguinated," read on Belvedere, because Belvedere showed the collection of cells, derived from blood, after the disclosed placenta was drained of blood (that is, the Examiners stated, after it was exsanguinated). Applicant disagreed, stating that the term "exsanguinated," as used in the claims, meant removal of substantially all blood. The Examiners stated that claim language that clearly excluded the collection of cells from blood would be allowable over the cited art. Although Applicant believed the claims as discussed clearly distinguished cited art, they agreed to amend the independent claims to clarify that the placenta used in the method was processed so as to remove blood prior to the collection of stem cells, or other cells, from the placenta. The Examiners indicated that this

would be an appropriate course of action, but stated that a search would have to be done before a determination of patentability was made.

The Examiners suggested that Applicant file a Request for Continued Examination in order to have amended claims considered, and Applicant agreed.